

REPORT DOCUMENTATION PAGE

*Form Approved
OMB No. 074-0188*

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1. AGENCY USE ONLY <i>(Leave blank)</i>	2. REPORT DATE February 2004	3. REPORT TYPE AND DATES COVERED Annual (1 Feb 2003 - 31 Jan 2004)	
4. TITLE AND SUBTITLE Assistive Technology Research Center		5. FUNDING NUMBERS DAMD17-00-1-0056	
6. AUTHOR(S) John Toerge, M.D.		20040602 017	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) National Rehabilitation Hospital Washington, DC 20036		8. PERFORMING ORGANIZATION REPORT NUMBER	
E-Mail: jet2@mhc.edu and michael.j.rosen@medstar.net			
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012		10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES Original contains color plates: All DTIC reproductions will be in black and white.			
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited		12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 Words) The Assistive Technology Research Center, ATRC, is comprised of a set of interrelated research and development projects which apply modern technologies, in particular those which have been exploited in the military, to the practice of medical rehabilitation and technological support for independent living for individuals with disabilities. The Center seeks to work collaboratively to meet the particular mandates of the U.S. Army Medical Research and Materiel Command. Projects are physically conducted and administratively located in the departments of rehabilitation engineering and neuroscience at the National Rehabilitation Hospital. Individual researchers from several other hospital services and clinical professions are also involved. The ATRC takes advantage of a unusual combination of skills, facilities, and interest; specifically a strong community of r&d specialists in biomedical engineering and neuropsychology is positioned to undertake collaborative projects unlike those under way at more conventionall staffed laboratories. The projects whose progress is detailed in this report target the needs of individuals with head injury, stroke, spinal cord injury and developmental disabilities. These activities address the clinical techniques of phsychologists, occupational, and physical therapist, physicians and speech pathologists. The make use of technologies based particularly in software development but also in man-machine systems, human factors, biomechanics, telehealth, virtual reality methods, and instrumentation. Assessment and enhancement of motor and cognitive function; and support and measurement of functional performance are the prevailing research themes.			
14. SUBJECT TERMS Assistive technology, neuroscience, telemedicine, rehabilitation		15. NUMBER OF PAGES 51	
16. PRICE CODE			
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited

AD_____

Award Number: DAMD17-00-1-0056

TITLE: Assistive Technology Research Center

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CONTRACTING ORGANIZATION: National Rehabilitation Hospital
Washington, DC 20036

REPORT DATE: February 2004

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

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Introduction: Highlights, Changes, and Rationale

Highlights: Key R&D Outputs and Outcomes.

- Progress in the ongoing development of the Automated Neuropsychological Assessment Metrics (ANAM) has been dramatic in two areas.
 - Analyses detailed in last year's report have been completed. Findings on the day-by-day recovery of one of the largest concussion cohorts (nearly 800 baselines and 64 concussions) ever reported will appear as the lead article in the May 2004 issue of *Neurosurgery*. This paper represents many years of work on the part of ATRC investigators, as well as collaborating investigators from the DVBIC, Walter Reed Army Medical Center, and U.S. Navy.
 - Implementation of a feasibility demonstration of large-scale civilian application of one of the products developed in earlier years of this project – the ANAM Sports Medicine Battery (ASMB) – is well underway. Its focus is concussion surveillance and management for athletes in contact sports at 22 high schools in Fairfax County, Virginia. Unlike the previous studies, conducted at the US Military Academy at West Point and at Fort Bragg, both of which are highly disciplined and structured environments, the Fairfax County project should demonstrate that the current ASMB system is sufficiently robust and user-friendly that it can be incorporated into a civilian public high school setting. This includes demonstrating that ASMB can be administered effectively by athletic trainers and coaches using primarily pre-existing computer equipment already available in high school classrooms, and that ASMB data can augment traditionally-based clinical decision-making.
- The Virtual Mall, a simulated environment for study of social disorders, was refined to incorporate improved features. In particular, control of the virtual camera (the operator's vantage point) was improved. In the new version, the camera intelligently changes its position relative to the user's avatar increasing the realism and aesthetic appeal. Virtual *activities* were also defined to produce a context in users will apply real-world behaviors. Users engaged in searching the mall in to locate specified target objects will need to navigate through space occupied by virtual humans and inanimate objects. Placement and orientation of the virtual humans creates situations that are identical in terms of spatial properties but differ importantly in social implications.
- To date, 18 SLPs have used the ATRC-funded treatment enhancement software developed by engineers David Brennan and Linsey Barker in more than 200 clinical sessions with more than 130 individual inpatient clients at NRH. These therapists elected to use the tablet computer-based system as a matter of choice, in preference to the using the traditional paper and pencil assessment and therapy materials
- The Mobile Audio-Visual Intervention System (MAVIS) – a clinician's tool for rapid, convenient, and intuitive recording and immediate random-access playback of video and audio information – has advanced through and past the alpha prototype stage. Design decisions have been repeatedly refined based on initial clinical trials by four OTs with ten patients.

- AnthroTronix has created a partnership with Product Genesis, a design and manufacturing firm located in Boston, MA, to assist in the commercialization of Mission Control a unique, multi-modal computer interface for children with disabilities that can accommodate off-the-shelf and custom switches. Mission Control is expected to be available in the marketplace in early 2005 incorporating custom sensors developed under ATRC subcontract funding .
- The “Dynamic Brace” (Advanced Prosthetics and Orthotics Inc., Encinitas, CA), a custom-made AFO fabricated from multiple layers of high modulus carbon graphite, uses floor reaction mechanics that store energy during the terminal stance phase of the gait cycle and release energy during lift off. It compliantly constrains ankle motion in three planes. Gait analysis has now been completed with 5 subjects with 3 different neuromuscular disorders at the NIH Motion Analysis Lab. Analyses compared gait measurements using traditional AFOs and the Dynamic Brace. Stride length increased from 5.2 to 42.0%; velocity improved 5.2 to 67.0%; and endurance increased 30 to 90% in this subject group.

Changes During Year 4 and Proposed Changes for Approved NCEP (No-Cost Extension Period)

Staffing

- Dr. Rosen has stepped down as Director of the Rehabilitation Engineering Labs preparatory to a move to a position outside of NRH. He continues to direct the current ATRC grant through its completion during the NCEP.
- Dr. Trepagnier is completing her ATRC-funded work in Virtual Reality applications under contract to the Psychology Department at the Catholic University of America where she now holds the position of Research Professor.
- Tresa Roebuck-Spencer, Ph.D. has joined the project as a Senior Research Associate. Her CV is attached in Appendix 1.

Projects

- **The Boing! Ani-Mate project:** Work on this project was closed during year 4 and resources distributed to other ATRC activities. The VR and Multi-Modal Interface project, conducted under contract to AnthroTronix (see Research Narrative below) was complete at the end of year 4. A decision was made to apply for other funding to merge and continue these two pediatric-oriented project. Both have been driven by the need to make therapeutic interventions with children more engaging; to enhance them by incorporating more objective assessment; to facilitate remote “telerehab” interactions via the Web; and to provide immediate contingent video feedback to the exercising child. An NIH rfp was published in the Federal Register in the summer of 2003 (RFA-HD-03-014) inviting STTR and SBIR proposals on “Innovative Technologies for Pediatric Critical Care and Rehabilitation”. Because the Boing! Ani-Mate hardware and software had been developed at NRH under the ATRC; because the goal of the work had reached the point where user evaluation and technology transfer were the appropriate next steps; and because AnthroTronix will be better suited to pursue commercialization than NRH – the ATRC administration chose to pursue more continued and substantial funding for this work via an STTR grant to NRH with AnthroTronix as its commercial partner.

- **The Magic Walker project:** the project team and ATRC administration made a decision that resources earmarked for further development and experimental evaluation would better be more sensibly committed to a thorough analysis of its commercial potential. To this end, a contract has been signed with Brian Kon, President of Sterling Frazer Associates in Niagara Falls, Ontario. A copy of the narrative portion of the contract is attached in Appendix 2. It calls for that firm to evaluate the Magic Walker, in part via focus group sessions, to report on the probable market for it, and to evaluate the competing walkers and gait training aids. If the findings are positive, the NRH rehabilitation engineering labs, in cooperation with Magic Walker LLC (the student-initiated company that spun off from the Dr. Rosen's rehabilitation engineering design course at the University of Tennessee, Memphis to patent the Magic Walker), will pursue licensing ownership of the design to bring this product to market. The final deliverables from this project during the NCEP will be the report from Mr. Kon's firm and an recommendation to Dr. Healton, Director of the NRH Research Division, and Kim Read, CEO of Magic Walker, LLC, regarding redesign and commercialization of the walker.
- **The Harness Walking project:** The intended focus of this delayed-start project under the direction of Lauro Halstead, MD, has been evaluation and treatment of gait anomalies secondary to partial spinal cord injury, stroke, post-polio syndrome and other disabling conditions. At the start of year four, Dr. Halstead initiated an ATRC project which maintained this focus but shifted from harness walking (a topic which is being vigorously explored in the Lokomat-based experiments of Joe Hidler, PhD, at NRH, under other MRMC funding) to evaluation of a promising new orthosis design. The new title of the project is **Dynamic Bracing: Evaluating a Novel Approach to Lower Extremity Bracing for Individuals with Incomplete SCI and Other Neuromuscular Disorders**. This new implementation of the ATRC focus on gait was driven by two opportunities. The first was contact initiated by orthosis manufacturer Advanced Prosthetics and Orthotics Inc. of Encinitas, CA with Dr. Halstead to solicit his interest in evaluating their marketed AFO design, characterized by controlled passive elastic storage and release of energy. The second was the development of a research partnership between Dr. Halstead and senior investigators at the Motion Analysis Laboratory at the National Institutes of Health.
- **The Home Evaluation Kit (HEK) project:** The year-four focus of the project was to have been design, fabrication and evaluation of a portable (collapsible or roll-about or modular) device for use by para-professional aids as a tool for imaging and measuring critical aspects of living environments in preparation for return of a newly-disabled individual from inpatient treatment. As MAVIS, the visual feedback system for enhancing in-hospital therapy and training, emerged as a more substantial aspect of the Unobtrusive Sensing project (see Research Narrative below) than anticipated, it became clear that that system could serve purposes other than its original intent – in particular use as the primary component of the Home Evaluation Kit. The design process for MAVIS included considerable consultation with NRH therapists. One open-ended brainstorming session in particular made it clear that the intended clinician users could visualize a broader range of applications than the MAVIS engineering team (Justin Carter, Linsey Barker, Michael Rosen) had contemplated. The considerable MAVIS development progress reported in the year-four narrative should be read as HEK progress as well. The HEK narrative describes the experimental trials planned for MAVIS in the home evaluation setting for the NCEP.

Table 1
Projects Based in the Rehabilitation Engineering Service

<u>Project</u>	<u>Completion Date Proposed in Previous Annual Report</u>	<u>Actual Completion Date</u>	<u>Comments</u>
<u>Completed as projected</u>			
Boing! & Ani-Mate	End of year 4	End of year 4	STTR proposal submitted to NIH with AnthroTronix to extend this project
Magic Walker	End of year 4	On-site work completed.	Contract signed for study of market potential. Report due during NCEP.
VR and Gaze Monitoring Part B: Social Stimuli and Hemineglect	End of year 4	End of year 4	
VR Transfer and Multi- Modal Interfaces, under Contract to AnthroTronix	End of year 4	End of year 4	
<u>Changes from timeline projected in the Year 3 Annual Report</u>			
“Wired Independence Square” and Visual Feedback	End of year 4	End of NCEP	Expanded Visual Feedback component (MAVIS); difficulty recruiting subjects for WISq component.
VR and Gaze Monitoring Part A: “Virtual Mall”	End of year 4	End of NCEP	“Virtual Mall” development expanded.
Home Evaluation Kit	End of year 4	End of NCEP	Delayed to permit application of MAVIS prototype from Visual Feedback project.
Technology-assisted Wound Assessment	End of year 4	End of NCEP	Obstacles to completion of controlled study in VNA setting.
Technology for Enhanced Rehabilitation Interaction	End of year 4	To be extended into new ATRC	Development and SLP evaluation goals expanded.
Dynamic Brace Evaluation (was “Harness Walking”)	End of year 4	To be extended into new ATRC	In year 4, study begun of energy-exchange orthosis jointly with NIH biomechanics lab

Research Narrative

Projects based in the Rehabilitation Engineering Service

BOING! & Ani-Mate – A Home Exercise Arcade & Video Game Authoring System for Children with Disabilities

**Status: work under ATRC support closed at end of year 4.
Continuation and extension proposed under NIH STTR Program funding
with AnthroTronix. (See discussion above in the Introduction under Changes
During Year 4 and Proposed Changes for Approved NCEP)**

**Principal Investigators: John Noiseux
Co-investigators: Michael Rosen**

Project abstract:

What follows is abstracted from an STTR proposal submitted in October, 2003 to the National Institute on Child Health and Development in response to RFA-HD-03-014 from NICHD which calls for “Innovative Technologies for Pediatric Critical Care and Rehabilitation”. The proposed project, under the direction of present ATRC director Michael Rosen, PhD, and AnthroTronix CEO Corinna Lathan, PhD, will join the Boing! Ani-Mate work stream with technology development and evaluation at AnthroTronix that has been funded under contract from the ATRC and other federal sources (see narrative on Multi-Modal Interfaces and Transfer of Training from Virtual to Real Environments, below)

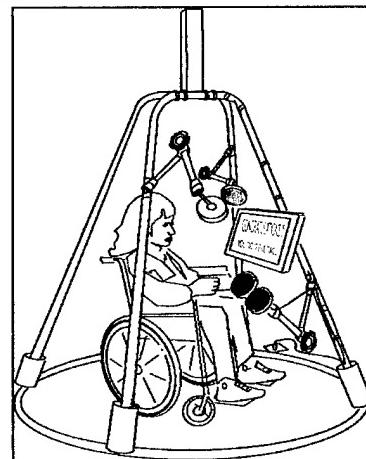
“The Goal of the proposed Phase I STTR project is to transfer Boing! and Ani-Mate to AnthroTronix, Inc. (ATinc), a small firm in Maryland, directed by Dr. Corinna Lathan, with a track record of work on rehabilitation technology for children. The components and features of their patented and SBIR-funded CosmoBot™ (a wireless interactive robot meant to motivate children in PT), CosmoWeb™ (a Web-based “teleplay” system which gathers performance information for display to therapists), and Mission Control adapted player interface systems will complement the characteristics of the NRH REL designs. An upgraded integrated system, labeled CosmoBoing! (Figure 1 below) in acknowledgement of its lineage, will be developed and subjected to initial

evaluation through the collaboration of REL and ATinc engineers with rehabilitation clinicians at NRH. ...

The specific Aims ...

1. Development: Refine and integrate existing prototype systems
 - a. Aim: Refine the mechanical features of Boing!. In particular: revise the motion sensor (which transduces exercise movement) for simplicity, reliability, and size reduction; and revise the “pulley arm” (which routes the bungee cord to the location of the exercising body part) for rapid, secure, convenient repositioning by the service provider ...
 - b. Aim: Revise the ATinc “Mission Control” player interface to provide four wireless, adjustable-placement target switches with individually-controlled contingent illumination and sound. These will provide physical targets for some exercises and new sources of contingent reward. [ATinc leads]
 - c. Aim: Interface the motion sensor signal with the on-site PC via “Mission Control” architecture ...
 - d. Aim: Integrate Ani-Mate and CosmoWeb™ games to run on a hub-site server; combine features of the clinician adjustment interfaces; and incorporate acquisition of performance metrics and display to clinician ...
2. Preliminary experimental trials: Demonstrate CosmoBoing! feasibility with a convenience sample of twenty four children in the inpatient National Center for Children’s Rehabilitation (NCCR) and the outpatient Cerebral Palsy Clinic at NRH; and with two groups of four “naïve” provider/evaluators (p/e’s) who will treat these children using the experimental system.
 - a. Technical feasibility: show that, based on formal survey of the p/es’ reactions after they use the system clinically with the patient sample, the CosmoBoing! can be a useful, adaptable platform for delivering clinically important resistance exercises to children with disabilities.
 - b. Clinical feasibility: formally survey the observations and opinions of the p/e’s regarding the clinical effectiveness of CosmoBoing! ...
 - c. Commercial feasibility: formally survey the reactions of the sample of children and the p/e group to determine whether they find it usable (in a human factors sense) and appealing enough to recommend purchase.

Figure 1: Mission Control integrated into CosmoBoing!



Magic Walker w/ Brakes

**Status: on-site work completed. Market study in progress under contract.
Report from that study will be final deliverable.**

Principal Investigator: John Noiseux

Co-investigators: Richard Keller, Michael Rosen

Project abstract:

The Magic Walker was designed at the University of Tennessee. It is a gait trainer / walker device that provides a child with support in the upright standing position. The child's weight is partially born on the walker seat and partially supported by the child's legs. The amount of support received can be customized based on the needs of the child. Steering of the walker is achieved by flexion of the trunk laterally. The mechanical coupling of steering to lateral trunk flexion leaves the upper limbs free for other tasks or for the child to stabilize himself / herself. The utilization of lateral trunk flexion, in contrast to rotation, is what most clearly distinguishes this design from other gait trainers / walkers. The main objective of the Magic Walker Brake Development project is to incorporate a brake system into the present design of the walker. This will enhance safety and may increase the marketability of the design. In particular, it will permit the Magic Walker to be used (with supervision) in an outdoor setting where inadvertent access to down slopes requires automatic activation of the brakes.

Progress:

See Project Changes under Introduction above.

Unobtrusive Functional Assessment

Status: to be completed in NCEP

Principal Investigator: J. Carter

Co-investigators: M. Rosen, L. Barker

As in Year's 1-3 reports, this project incorporates two parts, the Wired Independence Square project (WISq), and the Mobile Audio-Video Intervention System (MAVIS) project (formerly referred to as Visual Feedback). This report will present each of these projects independently.

WIRED INDEPENDENCE SQUARE

Project abstract:

Assessment of patients' functional status in a rehabilitation setting is typically done by an observing therapist using a subjective rating scale such as the FIM, Functional Independence Measure. As a method to introduce objectivity and "ecological validity" into the assessment process, ATRC engineers at NRH installed sensors into the Independence Square (a real-life home and community setting) which was constructed in the hospital in March 1998. The aim of the project is to add objective data to a patient's chart without requiring additional time or effort from the physical, occupational, or speech therapist.

Year 4 Progress and outcomes:

The main accomplishments of Year 4 follow:

- received Army IRB approval 6-10-03
- collected test data from 2 control participants
- received MedStar and Army approvals for expanded inclusion criteria
- collected data from 3 of 5 subjects

The majority of effort in Year 4 went toward recruiting subjects for the 5-subject pilot study. Due to the longer than expected time for Army IRB approval, we were unable to begin recruiting subjects until mid-June 2003. At this time, NRH was experiencing an unusually low patient census and we were unable to recruit any subjects that met the selection criteria for our study. In order to address this lack of subjects, the research team met with clinicians to discuss amending the selection criteria in order to increase the probability of finding appropriate subjects. The team determined that increasing the acceptable age range of subjects from 50-70 to 60-80 would fit better with the patient population at NRH. After amending the criteria, we were able to recruit three subjects for the pilot study. Currently, we are in the process of recruiting and scheduling the final two.

In addition to searching for experimental subjects, it was also determined that the analysis of the sensor data may require normalized comparisons in order to find valid performance metrics. Two control participants were asked to perform the study protocol. These

participants were one male and one female from the rehab engineering service at NRH who were unfamiliar with the purpose of the study.

Completion Plan for NCEP:

Recruitment of the final two pilot study participants is underway. Each NRH patient who has a diagnosis of LCVA is being evaluated to determine whether s/he would be eligible for the study. We foresee the final two subjects being recruited and tested by April 1 after which data analysis will begin. Analysis will include examining the data collected from the sensors to identify trends across subjects. Any frequently observed characteristics (e.g. sequences of sensor “activations” [defined as an event such as opening or closing a cabinet that causes an on-off or off-on change of switch state], excessive gaps between activations, skipped activations, etc.) will be viewed as prospective bases for Performance Metrics which will be compared with the results from the AMPS assessments. (The Assessment of Motor and Process Skills, AMPS, is the clinical assessment metric we are using for comparison with our Performance Metrics.) From these results and comparisons, we will perform a Power Analysis to determine the number of subjects needed for the full study.

NCEP Deliverables:

- data from the 5-subject pilot study
- potential Performance Metrics to correlate with clinical AMPS scores
- Power Analysis to yield requirements for the full study
- identified protocol changes for the full study

MAVIS – MOBILE AUDIO-VISUAL INTERVENTION SYSTEM

Project abstract:

The purpose of the Mobile Audio-Visual Intervention System (MAVIS) project is to design a clinical tool to record and play back video and audio information in a simple, convenient, and intuitive way. This information can be edited to highlight certain aspects and can be saved for future use. The tool will be used in any environment (e.g. patient rooms and bathrooms, treatment areas, cars, homes, outdoors) *by clinicians with patients, family members, and other clinicians*. It will be used for education and training purposes such as patient treatment, family training, and clinical in-service education. While several commercial systems are available, MAVIS has several design features that make it unique, and as a custom-developed project is available to be integrated into other ATRC projects.

Year 4 Background, status and outcomes:

The main accomplishments of Year 4 follow:

Completed development of software package including a database for archiving videos

Built an alpha-prototype of the system

Performed ad-hoc testing of alpha-prototype with 6 clinicians and 7 clients

Identified initial usability and functionality limitations of the system

Iteratively modified software and alpha-prototype based on feedback from users

During Year 4, we incorporated information and preferences gathered from the multidisciplinary panel of clinicians into an alpha-prototype. This version of the system consists of a laptop

computer with a 15.7-inch screen mounted on the moveable arm of a wheeled Ergotron® pole. The pole also has an attached basket for storage and a gooseneck arm to which the camera is mounted. We chose a wired USB webcam instead of the proposed wireless camera primarily for image quality. (Clinicians also agreed that it would not significantly inhibit the system's usefulness.) The final piece of hardware is the remote control which allows the clinician to start and stop video recording while remaining close to the client.

For the software development of MAVIS, we upgraded to the C# programming language and the Microsoft .NET® development environment. Using this environment, we were able to take advantage of existing software modules while developing additional expandable software components that when combined make up the entire MAVIS software package. The package is comprised of the following components: Collection, Video Selection, Review, and Data Archiving. The Collection module allows for remote triggering to start and stop video collection and is interfaced with the Data Archiving module for data storage. The Video Selection module provides users with a search engine and the ability to choose videos to review based on date, treating therapist, keyword, etc. The Review module has two screens, a single video playback and a side-by-side playback for comparing two videos simultaneously. The Data Archiving module stores recorded videos in a database for future retrieval and data logging.

The system has been tested by 4 occupational therapists with their clients in both treatment and clinician education scenarios. Following each use, minor issues were raised by the clinicians (such as search methods and screen layouts) and changes were incorporated into the system. More substantive change requests have been logged and prioritized as written in the Continuation Plan.

Completion Plan for NCEP:

purchase and evaluate new cameras with increased video quality and speed (possibly with pan/tilt incorporated into the software and/or remote control)
add Data Output module to save videos on CDs, DVD, VHS tapes, and printouts
finalize and incorporate more sophisticated Usage Logging module to track usage statistics and basic usability data
customize remote control to reduce unnecessary buttons and increase simplicity
investigate benefits of Tablet PCs versus the current laptop PC
build beta-prototype (with Tablet if appropriate)

NCEP Deliverables:

- beta-prototype with updated software (although do we have \$ for another pole?)
- database of archived video segments
- protocol for clinical usage
- database of usage statistics

Virtual Reality Display and Gaze Monitoring to Investigate Impairments of Visual Processing of Social Stimuli

Principal Investigator: C. Trepagnier

Co-investigators: M. M. Sebrechts, R. Ramloll, L. Baker, M. Jones Paxton, M. Coleman, A. Finkelmeyer, W. Stewart

Part A: Virtual Environment for Assessment and Training of Social Skills – the Virtual Mall

Status: To be completed in NCEP

Project abstract:

Social perceptual deficits are a significant barrier to independence for many individuals with traumatic brain injury, stroke, and autism. This project will develop virtual environments, using the metaphor of a shopping mall, presenting social contexts in which persons with impaired social judgment can be observed as they make behavioral choices. The long-term goal is the development and evaluation of a clinically practical and ecologically valid assessment of social cognitive function and a rehabilitation modality to improve the ability of individuals with acquired or congenital social cognitive impairment to function in everyday environments.

Year 4 Progress & Outcomes

Project effort was almost entirely allocated to development, due to the truncated period during which the project was cleared for human subject testing by the three IRB committees through which it was required to pass.

During the development of the virtual characters a number of design decisions were made based on iterative testing by the investigators. Initial testing of the character behavior and animation in the application environment revealed the need to modify the 3D character model in order to attain acceptable levels of rendering performance. Modifications implemented included reduction of the number of polygons and revision of the texturing. The accomplishment of these modifications now allows us to increase the number of virtual characters without significant sacrifices in rendering speed or realism of character appearance.

We developed additional characters in order to gain in variety, flexibility and, ultimately, ecological validity of the application. We followed a modular approach in this process, making it possible to make changes in the appearance of the virtual human easily by applying different texture maps to a small number of basic 3D models. Thus far we have developed three basic models (male, female, child) and a number of different textures for each one.

Development has also continued on the actual mall environment. (See Figure 1 below for examples.) During informal inspection of a prototype model that was developed during the first year a number of problems were identified, and solutions to these issues were incorporated into a

new design with a new, enlarged floor plan. The new design, built using more flexible software, has eliminated a number of problems encountered with the earlier prototype. Due to differences between the modeling software that was used for the design of the first prototype and the software used to produce the current model, it was not possible to transfer parts of the original mall over to the new environment. In creating the new environment we have used a modular approach, allowing changes to the mall environment to be made easily should need for such changes be identified in further testing.

In addition to these technical improvements, the updated mall environment incorporated design specifications that were identified during conceptualization of the evaluation task (see below).

A focus of development effort was to improve software control of the virtual camera. During investigator tests of the training and prototype environments we determined that camera control needed to be modified to increase the realism of the simulation. This was mainly the case when participants controlled their avatar from an external third-person perspective, during which the camera appears to follow the avatar. In earlier software versions, the camera's position was rigidly fixed with regard to the avatar, often resulting in situations in which the camera could be located within other objects or walls of the environment. This was eliminated by allowing the camera to change its position relative to the avatar to avoid 'collisions' with other objects in the environment. In the new version the camera intelligently changes its position as a function of the user's avatar. These changes have increased realism and aesthetic appeal of the environment.

Virtual activities were defined in detail for the human factors trials. Our goal is to produce a context in which people will behave in ways representative of their real-world behaviors. Accordingly we will ask participants to search through the mall in order to locate specified target objects. The environment through which they navigate includes virtual humans and inanimate objects, placed at locations that require the participants to navigate around them in order to reach the target object. Placement and orientation of the virtual humans creates situations that are identical in terms of spatial properties (e.g. width of openings between humans and walls, or obstacles and walls) but differ importantly in social implications (e.g., passing between a person and a store window to which her back is turned, versus passing between two characters facing each other at a conversational distance). Choice of path and distance between the operator's avatar and obstacles (other humans and inanimate objects and walls) are interpreted as relating to non-disabled participants' perception of the ecological validity of this environment. We wish to determine whether control participants display sensitivity to the social implications of the contexts, and whether narration of their own activity suggests that they are treating the environment as analogous to the real world. We are particularly interested in the user's perception of the experience and feeling of presence. As described in the protocol, we will use qualitative methods to gain a picture of users' impressions, and feed these results back into the design. If data show adequate ecological validity, the environment will have potential as a tool for use in assessing and intervening with individuals with social impairments, including autism.

Now that we have received permission (January 23, 2004) to proceed with subject testing, we are recruiting control participants, and participants in the experimental group. Recruitment was not undertaken previously because of the brevity of the period for which approval was obtained, and uncertainty as to when re-approval would be obtained.



Figure 1a. Avatar in a CD shop.



Figure 1b. Avatar strolling around a car displayed in the Mall hub.



Figure 1c. Avatar in a restaurant.



Figure 1d. Another view of the avatar in a grocery store.



Figure 1e. Experimenting with the effect of avatar design on behavior. Here the avatar has been made transparent.



Figure 1f. Anaglyph view of virtual environment for creating '3D' environments that can be viewed through red-blue glasses when the scene is projected on a wall.



Figure 1g. Avatar in a grocery store meeting a virtual human

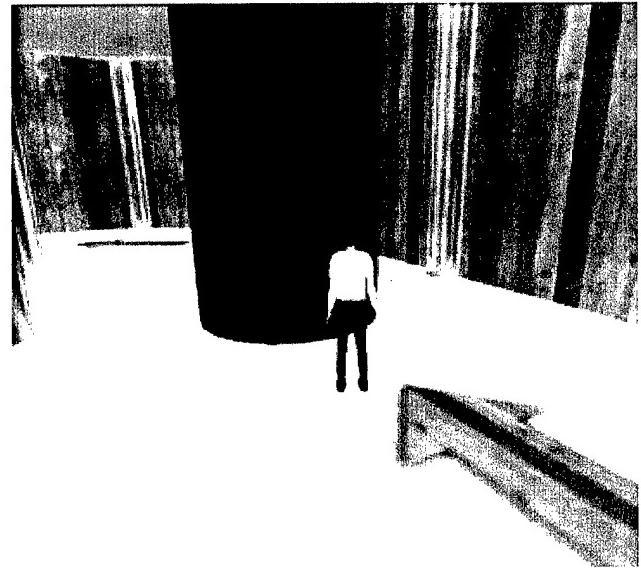


Figure 1h. An environment for training subjects to understand the function of the joystick and to get a feel of the device. In this environment, objects will pop up unpredictably ahead of the subject, to force the latter to learn complex navigation moves such as strafing. Subjects are involved in experiments only after achieving a set level of competency navigating in the virtual environment.

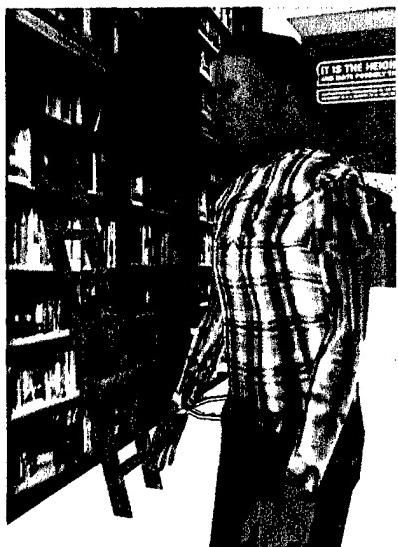


Figure 1i. User avatar meeting a virtual human in the first person view.

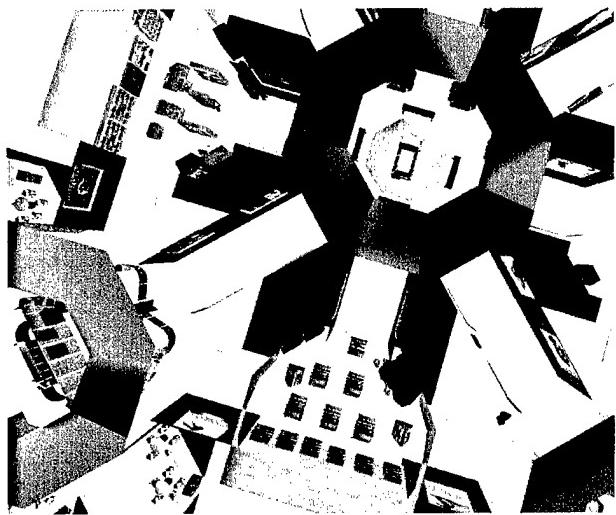


Figure 1j. A bird's eye view of part of the virtual. The car in figure 2 can be seen here in the upper right region of the picture.

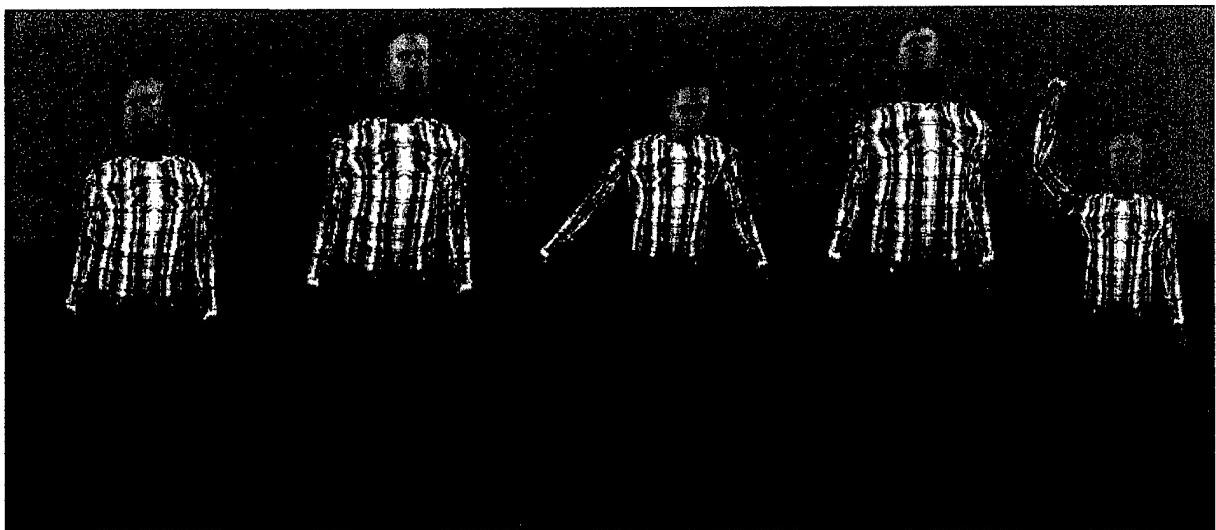


Figure 1k. Example behaviors of a visible virtual human: Looking left, Looking forward, Looking down, Looking up, waving. A virtual human can also produce sound bites and the sound. The environment supports 3D sound and speech appear to originate from the avatars.

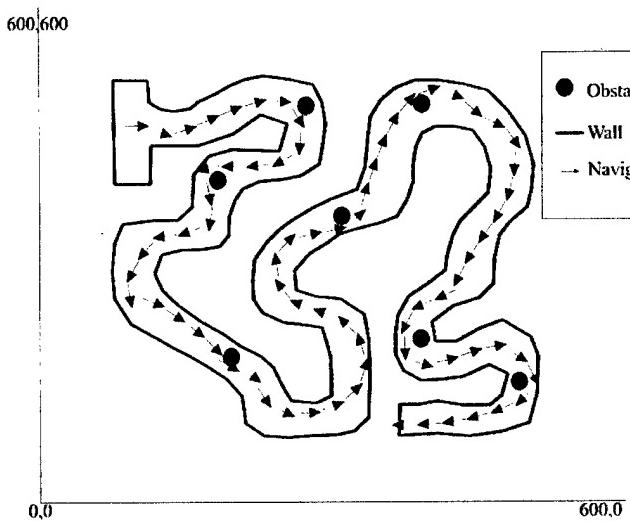


Figure 11. Illustration of the navigation trace of a subject that can be obtained.



Figure 1m. The force feedback joystick used as input device in the virtual environment. Whenever the user collides with an object, a force feedback is triggered and its magnitude indicates the intensity of the collision. Twisting causes the avatar to turn, pushing forward and pulling causes the avatar to move forward and backward, pushing to the sides causes the avatar to straf.

Figure 1: Illustrations of VRMall functionality

Plan for Completion in NCEP

VRMall is being tried out by members of the research group, to assure that no further modifications are needed before subject testing. Once the design is stabilized, we will compile quantitative scores of individuals with and without disability in order to compute a power estimate for formal evaluation of sensitivity and specificity of the Virtual Mall as an assessment of social impairment. Analysis of these data will provide an indication of whether and how to modify or develop the assessment further. We will use off the shelf spatio-temporal data analysis software to study our data.

We have explored possibilities for collaboration with small-business-based developers of animation and visualization technology. We have at present a relationship with a photo-realistic animation developer, who is collaborating with us in the context of another project. The outcome of the human factors trials supported by the present funding will be evaluated to determine whether we should proceed in that direction in seeking future funding for this work from other private and federal agencies. We have also met with a company that has a method for 3D display without requiring instrumentation on the viewer, and have seen other approaches to 3D visualization in the course of conference attendance. Pursuit of this aspect, as well as development of a natural language interface that will allow users to interact verbally with virtual humans, are also beyond the scope of the continuation plan for the present project, and may have a place in future plans for which other funding will be sought.

Once the experimental data have been collected and analyzed, a brief paper will be submitted to the Journal of Autism and Other Developmental Disorders.

If the results warrant it, the investigators will prepare a proposal to support development of additional functionality and acquire pilot data from an adequate sample of participants, in order to develop a proposal to the National Institute of Mental Health.

Part B: Gaze Monitoring to Investigate Impairments of Visual Processing of Social Stimuli

Status: Closed

Project abstract:

This arm of the Virtual Reality project looks at social aspects of the visual perceptual deficits associated with right hemisphere stroke. A remote eye-tracking system is used in a face- and object-recognition paradigm to ascertain whether learning and recognition of novel faces and objects is impaired in persons with a clinical diagnosis of left visuospatial neglect; whether these individuals display reduced gaze toward the left side of the images, and finally whether social stimuli (faces) are more resistant to neglect gaze deficits than non-social stimuli (objects).

Year 1 Progress and outcomes:

The work still needing to be carried out on the software for data reduction was completed, in order to make the process more rapid and resistant to human error. Two small programs were created to choose the files for analysis automatically and sort them into folders, rather than having that carried out by hand. In addition, further work was carried out to develop means to facilitate visualizing data, to support interpretation.

Graduate students were trained in the administration of the Behavioral Inattention Test, and in the administration of the study protocol, including operation of the eye tracker and procedures for scheduling, consulting records and filing results, and interfacing with the neurologist who provides the clinical examination.

There was a brief period during which the study had permission to recruit patients. Graduate students working on the study attended grand rounds and met with medical and therapy personnel to familiarize them with the criteria for study participation. Unfortunately only two patients meeting the study criteria were identified during the period between receipt of the Army IRB approval and expiration of the MedStar IRB approval. The study was re-submitted for IRB approvals. Approval to resume data collection was received January 23rd, 2004, too late to make further progress for the purposes of this report.

Home Evaluation Kit

Status: to be completed in NCEP

Principal Investigator: J. Noiseux

Co-investigators: J. Carter, L. Baker, C. Ellis, M. Rosen

Project abstract:

The outcome of this project will be a practical durable portable home evaluation kit, HEK, which can be carried into a client's home to evaluate the site for its compatibility with special needs and assistive technology. Its purpose will be to allow a home evaluation to be conducted by a trained technician, health aid or family member objectively and efficiently so that it becomes financially feasible under current restricted reimbursement. Thoroughness and objectivity will be essential to determine essential modifications, determine family training needs, select assistive devices for/with the patient, and plan define discharge criteria.

Year 4 Progress and outcomes:

See Project Changes in Introduction, page 7.

Completion plan:

As noted in the Introduction, page 7, the MAVIS system developed in the Unobtrusive Sensing project is potentially applicable to home evaluation, in addition to its original purpose as a tool for enhancing therapy by providing instantly accessible visual feedback of patient task performance. Applied to home evaluation, MAVIS – either in hand-carried or rollabout form – would be brought to a patient's home by a paraprofessional trained for this function. This "home tech" would capture video clips of key aspects of the physical environment, guided live by a professional rehabilitation engineer located remotely at her/his in-hospital setting ("hub site" in the language of telehealth). To make this use of the system feasible, the MAVIS-equipped computer (at the home, used by the home tech) will need to be linked to the hub site rehab engineer's computer via the Internet. The engineer will have streaming video from the MAVIS camera and be in two-way audio contact with the home tech to guide the selection of home areas to be imaged (and measured). The NCEP workplan for this project will incorporate the necessary technology development steps and in-home evaluation trials. The major elements of this protocol will include the following:

- The MAVIS software will be modified as needed to run concurrently with NetMeeting so that the hub site rehab engineer will be able to share the in-home computer's desk top, thereby visualizing the inside of the home.
- The MAVIS computer (laptop or tablet) will be equipped with a broadband wireless internet access card (Verizon Wireless BroadbandAccess service via the PC 5220 PCMCIA card).
- The in-home hardware will include portable camera-mounted floodlighting as needed to facilitate capture of acceptable images in uneven and uncertain lighting.

- A preliminary protocol for interaction between the home tech and the rehab engineer will be developed by rehab engineer, John Noiseux.
- An OT student, student nurse, or biomedical engineering student will be recruited to function as the paraprofessional home tech for the purpose of this study.
- Five homes will be identified for trial use of the system. At least the first three will belong to members of the Rehab Engineering Labs staff. They will be selected for convenience and to include a range of potential challenges. If the outcome of the first trial runs is sufficiently positive, the final two evaluation sites will be the living spaces of actual NRH inpatients selected by collaborating clinical staff. (Since this is an open study, meant only to characterize the advantages and obstacles to successful use of MAVIS as a home evaluation kit without a formal experimental protocol, it will be appropriate for senior NRH clinicians to elect to use the prototype system in the homes of their patients if, in their judgment, it may have value for their care and discharge planning.)
- In each home, John Noiseux will undertake a complete home evaluation mediated through the Web-enabled MAVIS and the actions of the novice home tech. The data from this workplan will consist of John's observations regarding the successes and difficulties of "tele-evaluation of homes". Procedures and minor software features will continually modified as needed to improve the quality and speed of interaction and data collection.
- A small team of Rehab Engineering Labs staff and NRH clinical staff, facilitated by John Noiseux, will review the MAVIS video clips and procedural observations. Project outputs will consist of determination of the feasibility of clinical tele-evaluation of homes; fiscal feasibility – given typical compensation level for a suitable home tech and the expected time for an experienced hub-spoke team to complete a tele-evaluation; and design specifications for improved system hardware, software and procedures.
- Findings will be submitted for presentation at the national conference of the American Telemedicine Association in the Spring of 2005.

Multi-Modal Interfaces and Transfer of Training from Virtual to Real Environments

Status: complete

Principal Investigator: Corinna Lathan, CEO, AnthroTronix

Co-investigator: J. M. Vice

Project abstract:

Leveraging ancillary funding from both the Department of Education and NSF, AnthroTronix has completed testing of gestural interfaces used in therapy at Mount Washington Pediatric Facility. Supporting this research is the ATRC-developed sensor test bed developed in year three. The wearable sensors allow subjects to control toys and games while performing strength and range of motion enhancement exercises.

This project has two principal objectives: 1) To provide children with disabilities opportunities to navigate and manipulate their environment using advanced interfaces; and 2) To explore the use of virtual environments to learn developmental tasks.

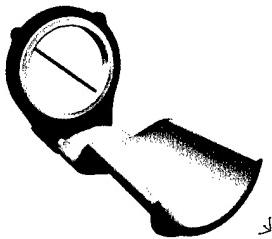
Year 4 Progress and Outcomes:

Objective 1: We completed a year-long study on gestural interfaces used in therapy at Mount Washington Pediatric Facility. In 2002, we created a sensor test bed for subjects to control a Nintendo game and a remote-control car with our wearable sensors while performing wrist extension exercises in order to increase wrist strength and range of motion. Using a single-subject, multiple baseline design, we investigated the child's motivation and the technology's data collection and activity correction capabilities. Preliminary analysis shows increased self-initiation on tasks and less corrective intervention required by the therapists, compared to baseline activities.

The research consisted of studies investigating the usability of the technology by therapists and the technology's effectiveness in motivating and addressing therapy goals. Although children were motivated to play the games while in therapy, a few limitations were observed when playing with Nintendo and a remote-controlled car. First, the therapist must structure the environment in which children operate the car and the therapist must play the Nintendo game with the child. These conditions require participation from a family member when used at home. Second, only the data from the sensors can be collected from the system: currently there exists no means for collecting data regarding the game's context in conjunction with sensor activation. Third, there is no means for programming the game to alter the content or level of difficulty to motivate the child and better address therapy goals.

Electro-mechanical sensors capable of detecting completion of the prescribed therapy exercises were developed under the ATRC. Sensors were developed after consulting with therapists, who identified wrist extension, and forearm pronation and supination as high-priority movements to be quantitatively, objectively measured with custom sensors. The pronation/

**Figure 1 Pronation/
supination sensor & brace**



supination sensor (Figure 1) consists of a ring and a potentiometer. The potentiometer's electrical resistance changes in proportion to the angle of the ring. The ring assembly is attached to an adjustable arm brace by metal rods.

A second sensor was developed to detect wrist extension (Figure 2). The wrist extension sensor consists of two gloves, one right handed and one left handed. The fingers of the gloves were removed while the thumb of each of the gloves

was left in place in order to indicate orientation of the sensor. A single bend sensor was sewn into the dorsal side of each glove. The bend sensor's electrical resistance changes in proportion to the wrist angle. The user's arm is placed in the same arm brace assembly that was designed to mount the pronation/supination ring. The child's arm is secured in the brace with two Velcro straps.

AnthroTronix staff also developed several related gestural sensors for a National Science Foundation Phase II SBIR. For this project, a more robust and less restricting approach involved using sensors that will plug directly into Mission Control. The design team has examined a variety of sensors for detection of translational motion, in addition to angular tilt.

At this point, the following sensors have been researched for potential use:

- Accelerometers that are a cost-effective, widely used technology. Memsic accelerometers can be used in various orientations to capture a variety of gross movements, and can be calibrated in software.
- Both hobby and scientific Gyros. The hobbyist gyros output a Pulse Width Modulation signal meant to control a servo (s). Professional or scientific gyros tend to be cost-prohibitive.
- Magnetometers or digital compasses. These devices are also commercially available, and provide position and orientation information.

In addition, the design team created a joystick mount to enable the use of a joystick sensor. The joystick mount is made using SLA to create a lightweight unit that can be easily plugged into Mission Control. It consists of a small housing unit that accommodates a joystick. A soft foam ball is mounted to the top of the joystick to appeal to children using the sensor and to make it easier to grasp and manipulate. The base is made of 1/4" metal and has rubber feet to ensure that the joystick and housing do not tip or slide.

The joystick and card are commercial parts. Engineers encountered a number of challenges in designing the housing. The first design was made with Delrin and was designed to be machined. The initial housing was bulky, which led the design team to create a new design made for rapid prototyping. This design proved to be suitable to meet the needs and requirements of this sensor.

Objective 2: We continued to pursue the second objective through support of the "VR Buddy" project, which was initiated in 2002 by developing a system to use virtual environments for learning social and cognitive skills. We developed the mechanical interface and system to integrate VR environments with eye tracking and a mechanical "ride" to motivate and reward the

Figure 2 Wrist Extension Sensor



child for appropriate behaviors such as looking at faces. In 2003, engineers have provided technical support to the "VR Buddy" project.

In Feb. 2003, engineers provided technical assistance on eye tracking issues in the pod. Although the pod was designed to track children between the 10th and 90th percentiles of the proposed study group (m/f ages 2-4), the children tested were all on the upper end of the scale, with some exceeding initial maximum dimensions. (some of the children were as old as 7). The Pod was brought back to the AnthroTronix laboratory to for adaptation. The front end of the pod was remolded to allow the screen to be moved up approximately 3 inches and to raise the angle of the tracker for increased eye tracking of the subject. The aluminum frame that holds all of the equipment was rebuilt and the fiberglass shell was remolded. The pod was returned to NRH in April 2003. In September 2003, engineers evaluated child restraint issues. The child had too much space or "wiggle room" in the seat. The seat back was tilted to make the child less likely to lean or lift the head off the headrest. The screen was moved down one inch to decrease the viewing/tracking angle for the child.

In 2004, we will work on ways to restrain the head without confining and, therefore, scaring the child.

Commercialization Accomplishments:

AnthroTronix has created a partnership with Product Genesis, a design and manufacturing firm located in Boston, MA, to assist in the manufacture and commercialization of Mission Control. We expect that Mission Control will be available in the marketplace in early 2005. Mission Control is a unique, multi-modal computer interface that can accommodate off the shelf and custom switches. AnthroTronix expects to make available to the market some of the custom sensors developed under the ATRC grant .

Teleassessment of Pressure Ulcers and other Wounds

Status: To be completed in NCEP

Principal investigator: L. Halstead

Co-investigator: M. Terry, M. Rosen, D. Lauderdale

Project Abstract:

This project is Phase II of a two-part study that involves the use of telemedicine (TM) to treat people with wounds living at home. Wounds represent a significant and costly health-care problem for many home care individuals. At the present time, these individuals are managed by visiting nurses who generally do not have special expertise in the evaluation and treatment of wounds. The purpose of this project is to address this health care need by investigating three methods of treating persons with wounds at home by nurses and consulting wound care specialists (WCSs) employed by MedStar VNA. 180 patients will be divided into three groups with the assignment of 60 participants and their visiting nurses to each group made by chance. One group (Group A: telemedicine) will have visiting nurses who take digital photos of the patients' wounds to supplement weekly consults with the WCS. The second group of patients (Group B: non-telemedicine) will have visiting nurses who consult with a WCS each week but without the use of digital images. The third group of patients (Group C: control) will have visiting nurses who provide usual and customary care and obtain consults with a WCS as needed. To determine which of the three groups receives the most effective wound care, we will collect and analyze a number of types of data including wound healing time, complications, cost, number of nursing visits, and satisfaction of the participants, visiting nurses and WCSs. The collection of data began in April 2003 and is scheduled to be completed by August 2004.

Note: The total number of subjects may be somewhat less than the number cited above. A review of the original power analysis used to calculate the required number of subjects is currently being performed by a consulting statistician. This is described in more detail under the Continuation Plan.

Year 4 progress and outcomes:

Following approval by the MedStar Research Institute (MRI) and the Department of Defense (DoD) IRBs in February 2003, we were able to begin the primary goal of this project which is to enroll subjects in 1 of 3 groups –A,B, and C. All subjects are patients referred to the MedStar Visiting Nurses Association (VNA) for treatment of 1 or more wounds that meet the inclusion criteria outlined in the original protocol. Subjects in Group A are treated with telehealth using digital images of their wounds and weekly consults with wound care specialists (WCSs). Subjects in Group B receive weekly consults with WCSs but no telehealth while subjects in Group C are treated using usual and customary wound care. The purpose of the study is to determine which of the 3 groups receives the most effective wound care. As of mid-February 2004, 80 subjects, or one-half the original projected number of study subjects, were enrolled in the study. Distribution of the 80 subjects is roughly equal in each of the 3 treatment groups.

We have encountered several major barriers over the past year that have slowed the work of the project. These include: 1) Enrollment of subjects. There was a significant lag time between the initial training (December 2002-February 2003) of the visiting nurses selected to be in the study and the actual enrollment of subjects (April 2003). Because of this delay, we had to repeat some of the training and orientation sessions. The orientation sessions were essentially "buy-in" meetings to confirm the willingness of each nurse to participate in the study. To accomplish these sessions, it was necessary to schedule and often re-schedule the training classes and orientation sessions to accommodate the busy work day of the VNA nurses, in our study called Visiting Nurse Investigators (VNIs) --who are spread out across Northern Virginia, DC, and Prince George's and Montgomery counties in Maryland--as well as holidays, sick leave, delays due to weather and traffic, etc. Planning, scheduling, and completing all these meetings simply took longer than expected as the activities associated with participating in this study are "add-ons" to the regular work schedule for the VNIs. These delays were further compounded by some VNIs in groups A, B, and C leaving the VNA. These individuals were replaced with randomly selected backup nurses who then had to go through all the standard orientation and training sessions. In addition, although the agency continues to have a large volume of wound care cases, these cases may not enter the study either because they do not meet the study criteria or because they do not live in the VNIs' geographic unit and are therefore not assigned to the VNI; 2) Technical issues. The technical issues turned out to be more numerous and, frequently, more difficult to solve than we had anticipated. Although the cameras we are using (Nikon Coolpix 4500), are relatively easy to use -- especially in the automatic mode -- not everyone is equally gadget tolerant. While some visiting nurses were taking high-quality images after only a few training sessions, others required multiple sessions and, even then, their images were not always satisfactory without further technical adjustments and problem solving. Another task that took more time to accomplish than anticipated included uploading the images to the laptop. This required modifications of the software program and ensuring that images were identified and stored in the proper file. Finally, transmitting the images from laptops to the WCSs computers took more time than anticipated (the visiting nurses have to log on to the MedStar LAN in a MedStar office) and performing the consults in a timely manner was often difficult for the busy VNIs; and 3) Human factors. Some of these 'human factors' have already been alluded to in the obstacles described above so only a few additional ones will be mentioned here. A very prominent issue is the fact that the visiting nurses are being asked to play a research role in addition to their usual role as a home health nurse. Thus, they are wearing two hats, instead of their customary one. In this new role, they are the researchers' surrogates and carry the main burden of collecting the data and making the study successful: they need to explain the study, answer questions, obtain informed consent, and carry out all the tasks required of them by the protocol depending on which group they belong to. These tasks are often made more difficult due to the elderly nature of the population, the potential subjects' inability to talk to the primary researchers, and the requirement that they read a 7-page consent and a 2-page HIPPA form.

We have deployed a number of strategies to surmount these barriers. For example, some of the delays described above -- especially the turnover in nurses -- were anticipated. As a result, when we did the original random selection of nurses to be in the study, we purposely selected six or more per group instead of just four. Therefore, when a selected nurse dropped out of the study because he/she was leaving the VNA, we had a replacement nurse available to take his/her place. Another strategy, implemented at the beginning of the study, to make participation in the project

more attractive was to offer financial compensation to the "pay- per-visit nurses" whose productivity would be affected by their participation. In addition, because of the importance of the study to the VNA, the Agency agreed to absorb the cost of the salaried nurses (especially in groups A and B) whose productivity will also be adversely affected during the course of the project. In addition, the VNA offered low cost incentives or 'prizes' to the nurses who enrolled the most subjects per month and held special 'thank you' receptions for all participating nurses and staff. These small gestures helped improve moral and maintain interest in the study. Another very effective strategy to overcome some of the technical and human factor barriers alike, involved having the new engineer on the project, Ms. Donal Lauderdale, accompany each of the Group A nurses during a home visit. This permitted the engineer to make on-the-spot observations, do instant troubleshooting, and on-site training with the cameras and laptops. Finally, another stratagem has been to revise the informed consent to make it shorter (4 pp. instead of 7) and easier to read. This has been approved by the MRI IRB and is awaiting approval by the DoD IRB.

Completion Plan and Deliverables for NCEP:

Our goal for the coming year is to complete data collection by August 2004. We have begun a preliminary analysis of the data collected on subjects who completed their wound treatment and were discharged from the VNA's care and from the study. The purpose of this step is to ensure that all the data points built into the protocol have been properly collected and can be retrieved for the required analyses. At the present time, we anticipate that the analysis will include a nonlinear, hierarchical, mixed model that will test the main hypothesis of a difference between healing time between groups. A mixed model contains both random and fixed effects. An effect is fixed if the study contains all levels of interest. An effect is random if the levels are a sampling of levels. In this study, treatment group is a fixed effect, while Geographical Units (GU) and VNIs are random effects. The model is hierarchical because VNIs are nested within GUs and GUs are nested within treatment group. The unit of analysis is the wound. The correlation matrix will be corrected for the correlation of multiple wounds within one patient. Wound type (surgical, pressure ulcer, and stasis ulcer) will be treated as a fixed effect. The interaction between wound type and treatment group will be assessed. Patient satisfaction data will be analyzed using simple descriptive statistics. Responses to the open-ended questions will be analyzed for trends and specific comments/suggestions to improve wound care and the use of telemedicine. The power analysis calculated at the time the original protocol was written called for a total of 180 subjects. However, we have reason to believe that the target n was unnecessarily large to demonstrate significance of the outcome variables. With this in mind, we have requested the consultation of another statistician for a second opinion. Although the final results of this consultation are not available at this time, a preliminary estimate suggests that we may be able to demonstrate significance of the outcome variables of interest with a smaller number of subjects. Clearly, this could have a major impact on when the data collection will be completed. When this occurs, we will then be in a position to proceed with our data analyses as described above and begin preparations for disseminating results of the project. This will include presentations at local and national conferences and writing articles for submission to peer reviewed journals. One important outcome of the study already is the decision by the VNA to obtain digital cameras for most of their nurses and begin using telemedicine as a routine part of their home care treatments.

Technology for Enhanced Rehabilitation Interaction

Status: to be completed in NCEP and extended into new ATRC grant

Principal Investigator: David Brennan

Co-investigators: Linsey Barker, Amy Georgeadis

Project abstract

Within the last decade, computers have become increasingly more integrated into medical rehabilitation service delivery models. This project aims to develop and evaluate software used to provide enhanced rehabilitative treatment to persons living with disabilities resulting from stroke, traumatic brain injuries, and other neurologic conditions. The objective is to create a custom-designed system that can be used in both clinical and research applications to deliver cognitive and communicative diagnostic assessments and therapeutic interventions.

Year 4 Progress and outcomes

This work extends and enhances R&D efforts conducted under the NIDRR-funded RERC on Telerehabilitation that has investigated providing remote speech-language and cognitive rehabilitation to adult clients with neurologic impairments. The work stream presented here involves the development of digitized versions of existing paper-based therapeutic treatment and assessment materials. The materials have been integrated into a software package that serves as a “digital library” consisting of a wide variety of the assessment and treatment material used by Speech-Language Pathologists (SLP). This software is currently being used in two settings: (1) inpatient and outpatient clinical SLP treatment sessions and (2) an SLP telerehabilitation research study

- (1) *Clinical SLP Treatment:* The “digital library” software has been installed on two portable tablet computers and is currently being used by the inpatient and outpatient SLPs at NRH with a broad range of clients. To date, 18 SLPs have used the software in more than 200 treatment sessions with more than 130 individual clients. The tablet computers allow clients to interact naturally with material by “writing” with the stylus much as they would use a pencil or pen with a piece of paper. The tablet computers also allow clinicians to take the software to the clients rather than requiring them to move clients to a computer. Clinicians are able to work more efficiently, by carrying a variety of treatment materials with them digitally instead of needing to photocopy and carry individual pages from workbooks.

In planning future directions for this stream of work, two focus groups were conducted in fall 2003 with the NRH SLP service to collect feedback on future applications for the software and identify ways in which it can be expanded. Additionally, a working group of administrators, researchers, and clinicians has been formed to investigate ways to expand this use of technology throughout the NRH Network. This working group will also examine options relative to the marketing and commercialization of the software that has been developed.

- (2) *SLP Telerehabilitation Research:* As described in past reports, the RESPECT (REmote SPEech-language and Cognitive Therapy) software was designed to allow a clinician to administer computer-enhanced treatment to a remote client during a telerehab session. RESPECT was recently expanded to include the “digital library” software described above and is currently being used in a research project funded with NIDRR support. This project consists of a series of longitudinal case studies to investigate the effectiveness of 18-sessions of SLP therapy delivered remotely using the RESPECT system to adult subjects with neurological impairments.

In conjunction with this work, an NIH-R21 Exploratory/Developmental Bioengineering Research Grant has been submitted to the National Institute on Biomedical Imaging and Bioengineering at NIH and is currently under review. The proposed project will further the development and usability testing of the RESPECT software with the eventual goal being technology transfer of an open-ended platform for providing a wide variety of remote rehabilitation interventions for clients with neurologic impairments.

Completion and Continuation Plans

This project will be consolidated so as to focus on traditional face-to-face treatment modalities. The telerehabilitation components of this project will move forward with funding from the RERC on Telerehabilitation as well as from other external sources.

During the extension period, the work plan for this project will proceed in two parallel streams. First, the current clinical use of the software by the NRH SLP service will continue and the frequency of its usage will be monitored. Additionally, efforts will continue relative to the clinical expansion and potential commercialization of the system

Second, a detailed and formal set of Design Specifications for the next-generation of the software system will be developed. These specifications will be based on prior research and development experience as well as on the outcomes of focus group sessions. In addition to those sessions conducted during the fall of 2003, additional sessions will be held with groups of NRH clinical and research staff to investigate other applications for which this work may have an impact. Outcomes from all of the focus groups will be assimilated and compiled into a technical report outlining various ways in which modern computer technology can be integrated into the clinical rehabilitation setting.

The Design Specifications will outline how the next-generation of the software will enable the ongoing applications at NRH related to computer-augmented SLP treatment while also serving as a platform for additional clinical and research applications related to the treatment of survivors of brain injury. Emphasis will be given to expanding the material currently available in the “digital library” and leveraging features and functions of Tablet PCs such as wireless internet access, multimedia audio and video, and alternative input devices.

Note: This project will be among the projects proposed to the USA MRMC for extension into the next cycle of ATRC funding.

Dynamic Bracing: Evaluating a Novel Approach to Lower Extremity Bracing for Individuals with Incomplete SCI and Other Neuromuscular Disorders.

Status: to be extended into new ATRC grant

Principal Investigator: L. Halstead

Co-investigators: S. Stanhope (NIH)

Project Abstract:

Conventional ankle foot orthoses (AFOs) are typically made from polypropylene and can deform in variable and unpredictable ways. This has hindered studies of the mechanical properties of the orthoses and the functional assistance they provide during activities of daily living. A newer AFO design, called the Dynamic Brace (Advanced Prosthetics and Orthotics Inc., Encinitas, CA), is made from continuous carbon fiber and consists of semi-rigid tibial cuff and footplate components connected by two deformable posterior longitudinal struts. This Dynamic Brace has design and stiffness characteristics that allow for the storage and release of mechanical energy as it deforms and returns to its resting state during gait. Comparisons of ambulation of 5 subjects (2 with incomplete SCI, 2 with Charcot-Marie-Tooth, and 1 with post-polio syndrome) were made between conventional orthoses and Dynamic Braces. Gait parameters evaluated were swing to stance ratios, stride length, velocity, and endurance. Assessments were made using computer analyses of digital videos. Evaluation of endurance was supplemented with subjective ratings. Data for all 5 individuals were analyzed for the average (and range of) changes and demonstrated marked improvement for each parameter. Limitations of this brace design include labor-intense fabrication, length of training and unsuitability for persons with complete paralysis of both legs and with moderate to severe spasticity. In 2 additional subjects with post-polio syndrome, the Dynamic Brace contribution to net ankle moments during ambulation was studied at the NIH Motion Analysis Laboratory. An analysis of these data indicated that the dynamic AFO allows users to decrease muscle use or amplify existing muscle use in order to enhance function. For selected individuals with lower limb paresis, this approach to bracing appears to offer some advantages over conventional orthoses for providing more independent, effective and efficient ambulation. The next goal for this project is to determine if the design and properties that make the Dynamic Brace effective can be replicated and enhanced using 'rapid prototyping' technology. This phase will be carried out in collaboration with researchers at NIH and the Department of Mechanical Engineering at the University of Texas, Austin.

Year 4 progress and outcomes:

A variety of injuries, disorders and diseases affecting muscle and nerve function can cause sufficient lower extremity weakness that impact gait performance. Some individuals with weakness may be unable to ambulate, while others have a limited ability to walk. Frequently these individuals are prescribed orthotic devices to assist their ambulation. In 2002 alone, Medicare expenditures for prosthetic and orthotic devices reached \$900 million. Ankle-foot orthoses (AFOs) are the most common type of orthosis prescribed to assist foot, ankle, and even

knee function during gait. AFO designs can vary in the shape and length of the foot component as well as the stiffness and length of the tibial component. The same patient may be prescribed very different AFO designs by various health care practitioners that can result in very different functional outcomes. This occurs because the selection and design of AFOs tends to be based on clinical experience rather than scientific evidence. Thus, there is clearly a need to identify causal relationships between specific design characteristics and gait performance. In addition, research is needed to establish the selection criteria for matching the optimal design characteristics to an individual's impairments in order to maximize the functional benefit of the device.

To address these needs, the initial efforts of this project have focused on studying a relatively new AFO that is called the Dynamic Brace and incorporates several novel characteristics into its design. The Dynamic Brace (Advanced Prosthetics and Orthotics Inc., Encinitas, CA) is custom-made from multiple layers of high modulus carbon graphite fiber that can be molded into lightweight AFOs. These braces are strong but pliable and use floor reaction mechanics that store energy during the terminal stance phase of the gait cycle and release energy during lift off. They provide active control of ankle motion in three planes, control the tibia, and facilitate knee extension. A custom mold of the individual's limb or limbs is made to serve as a negative for fabricating the brace that is designed using computer assisted modeling. Training with the finished brace may take anywhere between several hours to several months depending on the age of the subject, the underlying neurological disorder, and residual strength and weakness of the legs as well as the arms. Gait parameters were analyzed for 5 subjects with 3 different neuromuscular disorders. These analyses were made after each subject completed training and was using the Dynamic Brace on a regular basis. The analyses compared gait measurements obtained from digital videotapes of subjects using traditional AFOs and the Dynamic Brace with the exception of endurance that was based on each individual's subjective estimate of change. The subjects included 2 individuals with SCI, 2 with Charcot-Marie-Tooth and 1 with PPS. Three were women, the ages ranged from 32 to 60 years old and the duration of disability from 8 to 52 years. All the subjects were ambulating at the time of attaining their Dynamic Brace and all had significant weakness in lower extremity muscles that made walking slow, energy inefficient and often unsafe. The major gait abnormalities included instability of the ankle and knee, marked genu recurvatum, and foot drop.

Gait parameters evaluated were swing to stance ratios, stride length, velocity, and endurance. Assessments were made using computer analyses of digital videos. Evaluation of endurance was supplemented with subjective ratings. Data for all 5 individuals were analyzed for the average (and range of) changes for each parameter. Swing to stance ratios improved 5.8 % (3.0-11.7%), stride length increased 23.8 % (5.2-42.0%), velocity improved 38.7 % (5.2-67.0%), and endurance increased 69% (30-90%).

The potential advantages of the Dynamic Brace are that they are strong but lightweight, they use a variable floor reaction footplate (or rocker bottom), they have a dynamic response to floor reaction mechanics, and they provide triplanar control of foot-ankle-knee motion. In addition, they have the potential to stabilize and prevent deformities, improve static and dynamic balance, and improve metabolic and physiological efficiency. While there are a number of potential advantages to the Dynamic Brace, there are also several potential disadvantages. In contrast to a conventional AFO, which typically can be used after limited formal instruction, the Dynamic Brace can require several days, weeks and even months of training because they are fairly rigid and it takes time to get used to the combination of a variable floor reaction footplate (or rocker bottom) and the reasonably "forceful" dynamic response to floor reaction mechanics. As one

subject said, "At first, you feel as though you are walking on stilts with springs." The result is a sensation of precarious imbalance that takes different people different amounts of time to adjust to. However, once mastered, as another subject said, "The brace is like magic. You feel like you are walking with wings." Another potential disadvantage that is related to the training is the need for substantial subject commitment. Other disadvantages are the special fabrication, limited availability and the expense. Because of the labor-intensive custom fabrication, each brace may cost between \$4-6,000 dollars.

Based on this experience, we believe good candidates for the Dynamic Brace are those with fair to poor plus strength of one or both lower extremities with fair to good hip strength. Other characteristics of good candidates are absent to mild spasticity, absent to mild contractures of the ankle, knee and hip and a stable or slowly progressing lesion. Good arm strength is necessary if the subjects use canes or forearm crutches. Individuals who are not good candidates for this brace are those who have complete paralysis of both legs above T-12, subjects who have moderate to severe spasticity and contractures, and individuals with a rapid, progressive lesion.

In addition to these preliminary clinical studies of the Dynamic Brace, we performed a more sophisticated assessment of the brace at the NIH Motion Analysis Laboratory. This research focused on bench testing of the stiffness of the braces and the contribution of the Dynamic Brace to net ankle moments during gait in 2 subjects with lower extremity weakness due to post-polio syndrome. The results of these analyses demonstrated that the consistent deformation patterns of this AFO in bench test and walking trials suggest that the stiffness model developed in bench testing is valid for use in gait trials.

The analysis of the ankle moment curves indicates that the dynamic AFO allows users to decrease muscle use or amplify existing muscle use in order to enhance function. Different subjects may benefit differently from using this brace. Subject 1 was able to decrease his net muscular contribution to the net ankle moment, yet maintain the same functional level, while Subject 2 maintained the same net muscular contribution level with improved functional outcomes. This measurement capability is a first step towards quantifying the contributions from advanced assistive technologies.

Continuation Plan:

Based on the experience over the past year, we have decided to expand the research effort with support from the new ATRC appropriation funds into a new project to develop a prototype AFO brace called DYNAFO. Our collaborators will include key staff and resources from NIH and the Mechanical Engineering Department, University of Texas at Austin. This project will contain 2 phases having 4 related research objectives over a period of 4 years:

Phase I is a 12-month study designed to determine the feasibility of producing a suitable DYNAFO using Selective Laser Sintering (SLS) rapid prototyping technology. SLS is a powerful solid freeform fabrication technology developed at the UT-Austin and now commercialized by 3D Systems. It is a manufacturing technology for producing complex-geometry parts directly from computer models without the need for human intervention. In the SLS process, an object's computer-aided design (CAD) model is mathematically sliced into thin layers. The object is then created by selectively fusing sequentially deposited layers of material powder with a high-powered scanning laser beam. Each scanned layer represents a cross section of the CAD model, with successive layers being fused until the desired object is formed. SLS has three very unique features that make it an extremely powerful manufacturing technology: 1) the

process is more automated than current labor-intensive techniques and can produce complex prototypes in a fraction of the time; 2) the process supports online customization demands since increased shape or geometric complexity has minimal cost penalty during manufacturing; and 3) the use of multiple materials in SLS offers the possibility of manufacturing compositionally heterogeneous or functionally graded components, which will allow us to vary the mass distribution and control the stiffness characteristics throughout a customized DYNAFO orthosis. These features proved advantageous during the successful application of SLS techniques to design and manufacture compliant transtibial sockets, and are ideal for the proposed DYNAFO initiative in which various design concepts and functional properties can be quickly manufactured and evaluated. Feasibility will be demonstrated by evaluating experimentally and theoretically determined design concepts by altering the geometric shape and material properties and comparing the performance of a prototype DNYAFO with an existing commercial carbon fiber dynamic orthosis.

Phase II effort will consist of three key initiatives and will commence only upon successful demonstration of feasibility during the Phase I effort.

Initiative I will focus on developing a method for rapidly and non-invasively determining the most effective anatomically-based geometric shape of the DYNAFO directly from the subject's lower extremity anatomy.

Initiative II will develop a method for altering the DYNAFO's performance characteristics without significantly altering the anatomically-based geometric shape.

Initiative III will perform a clinical investigation on the influence of the DYNAFO's design characteristics on gait biomechanics and functional performance during simulated daily activities of normal and impaired patients.

Projects Based in Neuroscience

Automated Neuropsychological Assessment Metrics (ANAM): Psychometric Development and Integration into Military and Civilian Studies of Cerebral Concussion and Psychopharmacologic Treatment of Brain Injuries and Diseases

Status: to be completed in NCEP, extended into new ATRC grant, and continued via other research funding.

Principal Investigator: J. Bleiberg (NRH)

Co-Investigators: D. Reeves (U.S. Navy), T. Roebuck-Spencer (NRH), A. Cernich (NRH), R. Kane (Veterans Administration and NASA), T. Elsmore (Private Consultant), and K. Winter (U.S. Naval Computer and Telecommunications Station, Pensacola)

Progress Report:

There have been two primary outcomes this past year. First, is implementation of a demonstration project regarding the feasibility of large-scale civilian application of one of the products developed in earlier years of this project: the ANAM Sports Medicine Battery (ASMB). Second, many of the data analyses from projects initiated in prior years have been completed this past year and have resulted in a number of significant scientific presentations and publications.

This past year, the ASMB demonstration project cleared its final regulatory hurdle and was approved by the DoD IRB. Subject enrollment commenced in August of 2003, as scheduled. The project will demonstrate the feasibility of using the ASMB as part of concussion surveillance and management for athletes in contact sports at 22 high schools in Fairfax County Virginia. In previous studies, many of them presented or published this past year, we demonstrated the scientific properties of the ASMB as a concussion management and surveillance instrument. These studies, performed in collaboration with the Defense and Veterans Brain Injury Center (DVBIC), were, however, conducted at the US Military Academy at West Point and at Fort Bragg, both of which are highly disciplined and structured environments. In addition, the DVBIC settings incorporated significant numbers of medical and research personnel, and utilized designated spaces and dedicated computer equipment. The purpose of the Fairfax County project is to demonstrate that the current ASMB system is sufficiently robust and user-friendly that it can be incorporated into a civilian public high school setting. This includes demonstrating that ASMB can be administered effectively by certified athletic trainers and team coaches, using primarily pre-existing computer equipment already available in high school classrooms, and that ASMB data can augment traditionally-based clinical decision-making.

The second primary area of progress has been the completion of many of the data analyses which at the time of last year's report were ongoing or planned, and the conversion of these analyses into peer-reviewed scientific presentations and publications. Perhaps the most important of these is the paper scheduled to appear as the lead article in the May 2004 issue of Neurosurgery. This paper represents many years of work on the part of ATRC investigators, as well as collaborating investigators from the DVBIC, Walter Reed Army Medical Center, and U.S. Navy. The paper describes the day by day recovery of one of the largest concussion cohorts (nearly 800 baselines and 64 concussions) ever reported in the scientific literature. As can be seen from the below list of scientific presentations, in addition to the above-described paper, the additional data analyses completed and presented at scientific conferences this past year indicate that approximately six other papers are likely to result from the USMA and Fort Bragg data sets, with data analysis still ongoing and likely to yield additional findings.

Last year's progress report also described NRH's efforts to develop ANAM as a clinical instrument for monitoring cognition in systemic diseases such as lupus and fibromyalgia. The fibromyalgia project, which had just been approved for funding through the Department of Medicine at the Washington Hospital Center at the time of the writing of last year's progress report, has been ongoing since May of 2003. Recruitment for the study continues and is slightly beyond the halfway point; it is on schedule for completion during the NCEP.

The lupus projects, both with NIH and with the Albert Einstein College of Medicine, also are ongoing, and have produced an interim data analysis with significant findings regarding ANAM and its relation to traditional neuropsychological tests as well its relation to immune biomarkers of disease activity. To abstracts based on a portion of these preliminary findings, with NRH's Tresa Roebuck-Spencer as first author, and co-authors from NIH and Albert Einstein, have been submitted, with one accepted for the American Psychological Association meeting this coming August, and under review for acceptance for the upcoming Rheumatology Society 2004 meeting. We also are participating as co-investigators with Albert Einstein College of Medicine in the preparation of a Dana Foundation grant proposal to expand on pilot efforts this past year to relate changes in cognitive performance as assessed by ANAM with changes in NR2 antibody status. The Dana Foundation proposal will build on this past year's work by adding assessment of intactness of the blood brain barrier, in an attempt to identify whether cognitive impairment occurs as a consequence of the presence of the NR2 antibody, but primarily when NR2 positivity occurs in combination with a breach of the blood-brain barrier.

The above data analyses have produced a useful byproduct which we hope to exploit in future projects: Drs. Bleiberg, Cernich, and Roebuck-Spencer, have had intensive immersion in ANAM and traditional neuropsychological test data from large and diverse populations of healthy and diseased subjects. This has created two forms of tangible knowledge and experience. The first is a much more refined understanding of the database and data analysis approaches useful with ANAM data, as well as ideas for improving automation of all aspects of ANAM data management. The second is accumulation of clinical experience in the use of ANAM data, in combination with traditional neuropsychological test data and other clinical information, to assist clinical decision-making. There is both art and science in clinical decision-making, and the below-listed papers indicate our effort to quantify the scientific part of clinical decision-making, essentially identifying the sensitivity and specificity of ANAM in various situations.

Reportable Outcomes

Publications:

Bleiberg, J., A. N. Cernich, et al. (2004). "Duration of cognitive impairment following sports concussion." Neurosurgery **54**(4): 1-6.

Bleiberg, J., A. N. Cernich, et al. (submitted). "Automated Neuropsychological Assessment Metrics Sports Medicine Battery." Neuropsychology Review.

Bleiberg, J., D. Warden, et al. (2003). "Long-term impact of concussion on cognitive efficiency." Archives of Clinical Neuropsychology **18**(7): 740.

Brennan, D., Georgeadis, A., Baron, C., Barker, L. (2004). "The effect of videoconference-based telerehab on story retelling performance by brain injured subjects and its implications for remote speech-language therapy." Telemedicine Journal and e-Health [May issue, in press].

Cernich, A. N., J. Bleiberg, et al. (in press). "Prediction of concussion status using a computerized neuropsychological measure: A logistic regression analysis." Journal of the International Neuropsychological Society.

Cernich, A. N., D. M. Brennan, et al. (submitted). "Sources of error in computerized neuropsychological assessment." Neuropsychology Review.

Halstead, LS., Terry, M., O'Hare, P., Lauderdale, D., James, C., Obecny, J. (2004). "Technical Considerations in Developing a Home Care Wound Telemedicine Program." Home Healthcare Nurse. [May issue, in press]

Halstead, LS, Dang, T, Elrod, M, Convit RJ, Rosen MJ. (2003) "Teleassessment compared with Live Assessment in a Wound Clinic: A Pilot Study. Advances in Skin and Wound Care, 16:91-6.

Halstead, LS, (Ed.): Managing Post-Polio: A Guide to Living Well With Post-Polio Syndrome. 240 pg Washington: NRH Press, 1998. (Foreign editions in German and Italian published in 2002-2003).

Halstead, LS. (2003) Compassion-Based Rehabilitation. In Leskowitz, E (Ed.) Complementary and Alternative Medicine in Rehabilitation. St. Louis: Churchill Livingstone, 226-235.

Halstead, LS, Crittenden, DT, Nielsen, J-P, Loke, M. (2003). "Dynamic Bracing: A Novel Approach to Lower Extremity Bracing for Individuals With Incomplete Spinal Cord Injury and Other Neuromuscular Disorders." J Spinal Cord Med 26 (1):16

Ramloll, R. (2004) "Architecture of a tailorable VR system for targeted virtual reality therapies" submitted to the 17th annual conference on Computer Animation and Social Agents (CASA 2004) to take place the University of Geneva, Switzerland, July 7-9.

Ramloll, R. (2004) "Gaze data visualization: State of the art and future directions" for submission to the 8th International Conference on Information Visualisation (IV2004), to be held in London, UK, July 14-16. Proceedings of this meeting will be published by the IEEE Computer Society

Roebuck-Spencer, T. M., J. Bleiberg, et al. (in press). "Influence of age, sex, and education on the Automated Neuropsychological Assessment Metrics (ANAM)." Journal of the International Neuropsychological Society.

Roebuck-Spencer, T. M., W. Sun, et al. (submitted). "Assessing change with the Automated Neuropsychological Assessment Metrics (ANAM): Issues and challenges." Neuropsychology Review.

Rosen, MJ., Ed. (2004). Special Issue on Telerehabilitation. Telemedicine Journal and e-Health. [Summer issue, in press]

Savard, L, Borstad, A, Tkachuck, J, Lauderdale, D, and Brendan Conroy (2003). "Telerehabilitation consultations for clients with neurologic diagnoses: Cases from rural Minnesota and American Samoa". NeuroRehabilitation .18, 93-102.

Conference Presentations (with Proceedings):

Bleiberg, J. (2003). "Effects of Mild Traumatic Brain Injury (MTBI) on Human Performance: Symptoms and State-of-the-Art Assessment Methods." Chair, Symposium presented at the International Conference on Closed Head Trauma. San Juan, Puerto Rico.

Bleiberg, J., D. Reeves, et al. (2003). Neuropsychology as a Public Health Intervention. Symposium presented at the American Psychological Association, Toronto, CA.

Brennan, D., Barker, L., Georgeadis, A.. (2003, March). "Telerehabilitation for Delivering Rehabilitation Services at a Distance." Presentation at the IST Rehabilitation and Technology Seminar 2003, Rockville, MD.

Halstead, LS. (2003). "New Research and Clinical Management in Post-Polio Syndrome". Keynote presentations at: Post-Polio Support Group Conference of Northern Virginia; April 12.

Halstead, LS. (2003) "Dynamic Bracing: A Novel Approach to Lower Extremity Bracing for Individuals With Incomplete Spinal Cord Injury and Other Neuromuscular Disorders" at the Annual Meeting of the American Spinal Injury Association; Miami, FL, April 4.

Houston, B., Brennan, D. (2003, July). "The Telepractice Frontier for School-Based Services." Presentation at ASHA Schools 2003, Anaheim, CA.

Roebuck-Spencer, T. M., J. Bleiberg, et al. (2003). "Using computerized testing to track cognitive change following migraine: Comparison of two methods for assessing change." Archives of Clinical Neuropsychology 18(7): 802 [Abstract].

Rosen, M.J. (2003). "Unobtrusive Sensing of ADL Performance for Estimation of Functional Status." RESNA 26th Annual Conference, Atlanta, June.

Rosen, M. (2003). "It's the music, not the fingers: reflections on disability, assistive technology, and independence," presentation at Assistive Technology: Functional Applications, presented by Methodist Rehabilitation Center, The Center for Neuroscience and Neurological Recovery, and the Mississippi Department of Rehabilitation Services, Jackson, MS, August.

Rosen, M. (2003). "Telehealth and e-health systems as assistive technology. Independence: what is means and what it has to do with assistive technology." Presentations at Assistive Technology: Functional Applications, presented by Methodist Rehabilitation Center, The Center for Neuroscience and Neurological Recovery, and the Mississippi Department of Rehabilitation Services, Jackson, MS, August.

Trepagnier, CY, with Lathan, C., Sebrechts, M. M., Ramloll, R., Vice, M., Pettersen, M., & Rosen, M., (2003). "Design and Evaluation of a Virtual Environment for Teaching Nonverbal Communication". Platform presentation at CyberTherapy, San Diego, CA, January 20.

Other Invited Presentations, Demonstrations, Theses and Talks without Proceedings:

Santrach, S, Bowman, T., Trepagnier, C., Lauderdale, D. (2003). "Balancing the needs and objectives of research and service delivery in the quest for subjects R2 Case Study: Lessons learned." Poster presentation at CyberTherapy, San Diego, CA, January 19.

Trepagnier, CY. (2003). "Development and pilot study of method to train newly diagnosed preschoolers with autism to attend to and interpret faces, using eye tracking and contingent multimodal display – The Virtual Buddy." Invited Presentation at Meeting to discuss role of communication and computer technologies in autism. Telemedicine and Advanced Technology Research Center of the USAMRMC, Ft. Detrick, Frederick, MD. Monday, June 16.

Proposals Submitted and Awarded Based on ATRC Accomplishments:

Grants Awarded:

National Institutes of Health SBIR Phase I, awarded April 2003 to AnthroTronix

Department of Education Phase II SBIR, awarded September 2003 to AnthroTronix

National Institute of Mental Health, proposal submitted in response to RFA MH-01-010, RO1 awarded November, 2003

Proposals Written and Pending:

National Institute on Biomedical Imaging and Bioengineering (PA-03-058), NIH R21 Exploratory/Developmental Bioengineering Research Grant, submitted October, 2003 by the Rehab Engineering Labs, Brennan.

National Institutes of Health STTR Phase I, submitted November 2003, by NRH with AnthroTronix, Rosen.

National Institute on Disability and Rehabilitation Research, Field-Initiated Proposal, submitted December 2003, by NRH Rehabilitation Engineering Labs, Rosen

US Army Medical Research and Materiel Command, to be submitted March 2004 by the Research Division of NRH for renewed ATRC funding, Healtton.

National Science Foundation, “fast lane” proposal submitted January 2004 by NRH Rehabilitation Engineering Labs, Ramloll

Honors:

Halstead, LS. (2003). Invited to organize and lead a 3-person American medical team to train 20 Peruvian health care professionals to establish a Post-Polio Clinic in Lima, Peru. March 9-16.

Conclusions

PLEASE NOTE: All scientific and technical conclusions have been incorporated into the project narratives above.

Appendix 1: Roebuck-Spencer Resume

TRESA M. ROEBUCK SPENCER, PH.D.

Curriculum Vitae

Office Address:

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Home Address:

2275 Wheel Cog Place
Woodbridge, VA 22192

LICENSURE

Licensure in the District of Columbia, License # PSY 1000189

Licensure in the state of Texas, License # 3-1893 (inactive status)

EDUCATION

2000-2002	Baylor College of Medicine/The Institute for Rehabilitation and Research/ Brain Injury Research Center (APPCN-Accredited) Postdoctoral Fellowship in Clinical Neuropsychology
1999-2000	University of Chicago Medical Center Internship in Clinical Psychology (APA-Accredited) <i>Specialization in Clinical Neuropsychology</i>
1995-2000	San Diego State University/University of California, San Diego Joint Doctoral Program in Clinical Psychology (APA-Accredited) Ph.D. completed August 2000. Clinical Psychology with Specialization in Neuropsychology Dissertation Topic: <i>Assessment of interhemispheric functioning in children with heavy prenatal exposure to alcohol</i>
1990-1994	University of Houston, Honors College Bachelor of Science in Psychology, Summa Cum Laude Senior Honors Thesis: <i>A dual-task study: Incorporating the speech and manual dominance models</i>

HONORS AND AWARDS

1999	Research Society on Alcoholism Student Research Award
1999	Research Society on Alcoholism Student Merit Award
1998	Finalist, Research Society on Alcoholism Student Research Award
1998	Research Society on Alcoholism Student Merit Award
1997	Research Society on Alcoholism Student Merit Award

1997	Western Psychological Association Student Recognition Award
1990-1994	University of Houston Academic Recognition Scholarship
1990-1994	George and Mary Josephine Hamman Scholarship

PROFESSIONAL AFFILIATIONS

American Psychological Association
 APA Division 40
 National Academy of Neuropsychology
 International Neuropsychological Society
 Virginia Psychological Association

PROFESSIONAL ACTIVITIES

Program Committee Member for APA Division 40 (2004 – 2007)

CURRENT POSITION

2002-present	Senior Research Associate Neuroscience Research Center National Rehabilitation Hospital Washington, DC
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SUPERVISED CLINICAL EXPERIENCE

2000-2002	Baylor College of Medicine/The Institute for Rehabilitation and Research/ Brain Injury Research Center APPCN-Accredited Postdoctoral Fellowship in Neuropsychology <i>Directors:</i> Corwin Boake, Ph.D., ABPP; Walter High, Ph.D., George Ringholz, MD, Ph.D.
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Clinical Rotations:

Baylor College of Medicine
 Department of Neurology, Section of Neuropsychology and Behavioral Neurology; *Supervisor:* George Ringholz, M.D., Ph.D.

Ben Taub Hospital

Psychiatry Consult and Liaison Service; *Supervisor:* George Ringholz, M.D., Ph.D.

St. Luke's Episcopal Hospital

Physical Medicine & Rehabilitation; *Supervisor:* Norma Cooke, Ph.D.

Texas Children's Hospital, Pediatric Neurology Clinic

Supervisors: Lynn Chapiessky, Ph.D. & Karen Evankovich, Ph.D.

University of Texas, MD Anderson Cancer Center

Department of Neuro-oncology; *Supervisor:* Christina Meyers, Ph.D., ABPP

The Institute for Rehabilitation and Research (TIRR)

Brain Injury Rehabilitation; *Supervisor:* Corwin Boake, Ph.D., ABPP

1999-2000	University of Chicago Medical Center, Department of Psychiatry Clinical Psychology Internship, Clinical Neuropsychology Specialization <i>Training Director:</i> Neil Pliskin, Ph.D., ABPP
	<u>Clinical Rotations:</u>
	University of Chicago Medical Center, Department of Psychiatry Outpatient Neuropsychology Clinic; <i>Supervisors:</i> Neil Pliskin, Ph.D. & Ivan Torres, Ph.D.
	Outpatient Psychiatry Clinic; <i>Supervisors:</i> Joseph Fink, Ph.D. & Neil Pliskin, Ph.D.
	Cognitive Behavioral Therapy Clinic; <i>Supervisor:</i> Mark Reinecke, Ph.D.
	Outpatient Pediatric Neuropsychology Clinic; <i>Supervisor:</i> Scott Hunter, Ph.D.
	Tinley Park State Hospital Consultation Service at Psychiatric Inpatient Hospital; <i>Supervisor:</i> Ivan Torres, Ph.D.
	Weiss Memorial Hospital Inpatient Rehabilitation; <i>Supervisor:</i> Maureen Lacy, Ph.D.
1998-1999	Department of Veterans Affairs Medical Center, San Diego Neuropsychological Assessment Unit <i>Supervisors:</i> Dean Delis, Ph.D., Terry Jernigan, Ph.D., Mark Bondi, Ph.D., Greg Brown, Ph.D.
1998-1999 Clinic	University of California, San Diego, Gifford Outpatient Psychiatry Neuropsychology Practicum <i>Supervisor:</i> Robert Heaton, Ph.D., ABPP
1997-1998	University of California, San Diego, Medical Center Neuropsychiatry and Behavioral Medicine Unit (Psychiatric Inpatient) <i>Supervisor:</i> William Perry, Ph.D.
1996-1997	San Diego State University Psychology Clinic Child and Family Psychology Clinic <i>Supervisor:</i> Vanessa Malcarne, Ph.D.
1996	Department of Veterans Affairs Medical Center, San Diego Outpatient Mood Clinic <i>Supervisor:</i> John McQuaid, Ph.D.

RESEARCH EXPERIENCE

2002-present	Neuroscience Research Center <i>Senior Research Associate</i> National Rehabilitation Hospital
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2000-2002	Brain Injury Research Center <i>Neuropsychology Postdoctoral Fellow</i> Baylor College of Medicine/The Institute for Rehabilitation and Research <i>Supervisors:</i> Walter High, Ph.D., Corwin Boake, Ph.D., Angelle Sander, Ph.D., & Margaret Struchen, Ph.D.
1995-2001	Center for Behavioral Teratology <i>Graduate Research Assistant</i> Neuropsychological, EEG and MRI evaluation of children prenatally exposed to alcohol San Diego State University, Department of Psychology <i>Supervisor:</i> Edward P. Riley, Ph.D.
1994-1995	Developmental Neuropsychology Clinic <i>Research Assistant</i> University of Texas Mental Sciences Institute, Houston, Texas <i>Supervisor:</i> Deborah Pearson, Ph.D.
1993-1995	Cognitive Neuropsychology Laboratory <i>Undergraduate Research Assistant</i> University of Houston, Department of Psychology <i>Supervisor:</i> Merrill Hiscock, Ph.D.

TEACHING AND ACADEMIC ACTIVITIES

1997	Invited Reviewer Journal of the International Neuropsychological Society Alcoholism: Clinical and Experimental Research Perceptual and Motor Skills/Psychological Reports
1996-1997	Statistical Methods in Psychology <i>Graduate Instructor</i> Department of Psychology, San Diego State University
	Statistics Tutor Department of Psychology, San Diego State University

PUBLICATIONS

Roebuck-Spencer, T. M., Mattson, S. N., Marion, S. D., Brown, W. S., & Riley, E. P. (In press). Bimanual coordination in alcohol-exposed children: Role of the corpus callosum. *Journal of International Neuropsychological Society*.

Atchison, T.B., Sander, A.M. Struchen, M.A., Roebuck, T.M., Contant, C.F., Wefel, J.S., Novack, T.A., Sherer, M., & High, W.M. (In press). Relationship Between Neuropsychological

Test Performance and Productivity at 1-Year Following Traumatic Brain Injury. The Clinical Neuropsychologist.

Roebuck, T. M., & Mattson, S. N. (2002). Interhemispheric transfer in children with heavy prenatal alcohol exposure. *Alcoholism: Clinical and Experimental Research*, 26 (12), 1863-1871.

Mattson, S. N. & Roebuck, T. M. (2002). Acquisition and retention of verbal and nonverbal information in children with heavy alcohol exposure. *Alcoholism: Clinical and Experimental Research*, 26(6) 875-882.

Struchen, M. A., Atchison, T. B., Roebuck, T. M., Caroselli, J. S. & Sander A. M. (2002). A multidimensional measure of caregiving appraisal: Validation of the Caregiver Appraisal Scale in traumatic brain injury. *Journal of Head Trauma Rehabilitation*, 17(2), 132-154.

Sander, A. M., Roebuck, T. M., Struchen, M. A., Sherer, M. S., & High, W. M. Jr. (2001). Long term maintenance of gains obtained in post-acute rehabilitation by persons with traumatic brain injury. *Journal of Head Trauma Rehabilitation*, 16(4), 1-19.

Perry, W., Heaton, R., Potterant, E., Minnasanian, A., Roebuck, T., & Braff, D. (2001). Working memory in schizophrenia: Transient "online" storage versus executive functioning. *Schizophrenia Bulletin*, 27(1), 157-176.

Roebuck, T. M., Mattson, S. N., Riley, E. P. (1999). Behavioral and psychosocial profiles of alcohol-exposed children. *Alcoholism: Clinical and Experimental Research*, 23(6), 1070-1076.

Roebuck, T. M., Simmons, R. W., Richardson, C., Mattson, S. N., & Riley, E. P. (1998). Neuromuscular responses to disturbance of balance in children with prenatal exposure to alcohol. *Alcoholism: Clinical and Experimental Research*, 22(9), 1992-1997.

Roebuck, T. M., Simmons, R. W., Mattson, S. N., & Riley, E. P. (1998). Prenatal exposure to alcohol affects the ability to maintain postural balance. *Alcoholism: Clinical and Experimental Research*, 22(1), 252-258.

Roebuck, T. M., Mattson, S. N., & Riley, E. P. (1998). A review of the neuroanatomical findings in children with fetal alcohol syndrome or prenatal exposure to alcohol. *Alcoholism: Clinical and Experimental Research*, 22(2), 339-344.

Caroselli, J. S., Hiscock, M., & Roebuck, T. (1997). Asymmetric interference between concurrent tasks: An evaluation of competing explanatory models. *Neuropsychologia*, 35(4), 457-469.

Caroselli, J. S., Hiscock, M., & Roebuck, T. (1997). Webster's scattergram method: Usefulness for assessing the asymmetry of interference between concurrent tasks. *Journal of Clinical & Experimental Neuropsychology*, 19(2), 185-190.

Pearson, D. A., Santos, C. W., Roache, J. D., Loveland, K. A., Casat, C. D., Farwell, E. C., Roebuck, T. M., Lachar, D. (1996). Effects of methylphenidate on behavioral adjustment in children with mental retardation and ADHD: Preliminary findings from a study in progress. *Journal of Developmental and Physical Disabilities*, 8(4), 313-333.

BOOK CHAPTERS

Roebuck, T. M., Mattson, S. N., & Riley, E. P. (1999). Prenatal alcohol exposure: Effects on brain structure and neuropsychological functioning. In J. H. Hannigan, L. P. Spear, N. E. Spear, & C. G. Goodlett (Eds.), Alcohol and Alcoholism: Effects on Brain and Development, Lawrence Erlbaum: Mahwah, NJ.

MANUSCRIPTS UNDER REVIEW

Roebuck-Spencer, T.M., Sun, A., Cernich, A.N., Farmer, K., & Bleiberg, J. Assessing Change with the Automated Neuropsychological Assessment Metrics (ANAM): Issues and Challenges

Roebuck-Spencer, T. M. & Mattson, S.N. Implicit strategy affects learning in children with heavy prenatal alcohol exposure. Alcoholism: Clinical and Experimental Research.

Ringholz, G.M., Schulz, P.E., Roebuck-Spencer, T.M., Mosnik, D.M., McMurray, P., Bradshaw, M., & Appel, S.H. Prevalence and Types of Cognitive Dysfunction in Amyotrophic Lateral Sclerosis.

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Roebuck-Spencer, T.M., Bleiberg, J., Nowak, M., Lapteva, L., Yarboro, C., Weickert, T.W., Ph.D., & Illei, G. (2004). Use of computerized testing to predict neuropsychological status in lupus. Poster to be presented at the American Psychological Association, Honolulu, HI.

Cernich, A.N., Bleiberg, J., Roebuck-Spencer, T.M., Reeves, D.L., Ivins, B., Schwab, K., Brown, F., Warden, D. (2004). Computerized concussion assessment without baseline: Effect of interval and severity. Poster to be presented at the American Psychological Association, Honolulu, HI.

Roebuck-Spencer, T.M., Bleiberg, J., Cernich, A.N., Ivins, B., Schwab, K., Sun, W., Reeves, D.L., Brown, F., Warden, D. (2004). Influence of age, sex, and education on the Automated Neuropsychological Assessment Metrics (ANAM). Poster presented at the 2004 International Neuropsychological Society Meeting, Baltimore, MA.

Cernich, A.N., Bleiberg, J., Roebuck-Spencer, T.M., Ivins, B., Schwab, K., Reeves, D.L., Brown, F., Warden, D. (2004). Prediction of concussion status using a computerized neuropsychological measure: A logistic regression analysis. Poster presented at the 2004 International Neuropsychological Society Meeting, Baltimore, MA.

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Caroselli, J. S., Hiscock, M., Larkey, F., & Roebuck, T. (1994). Dual-task interference in right- and left-handers: Effects of handicapping the dominant hand. Presented at the International Neuropsychological Society, Cincinnati, Ohio.

RESEARCH SUPPORT

2002 - 2005

A Computerized Neuropsychological Battery for Parkinson's Disease: Applications for Population Surveillance, Early Detection, and Monitoring Disease Progression.

Department of Defense, U.S. Army Medical Research and Materiel Command, DAMD17-02-2-0032

Neuroscience Research Center, National Rehabilitation Hospital

The major goal of this project is to develop an effective and highly efficient computerized testing system for population surveillance, early identification, and clinical monitoring in Parkinson's Disease.

Role: Project Coordinator (PI – Joseph Bleiberg)

2003 – 2004

Development and Clinical Validation of a Children's Version of the Automated Neuropsychological Assessment Metrics (ANAM)

Department of Defense, U.S. Army Medical Research and Materiel Command
Neuroscience Research Center, National Rehabilitation Hospital

The major goal of this project is to develop, validate, and collect normative data for a computerized testing system designed for tracking subtle cognitive change in pediatric populations secondary to neurological disease progression and intervention.

Role: Principal Investigator

Appendix 2: Sterling Frazer Contract Excerpt



MARKET RESEARCH CONSULTING AGREEMENT

This Agreement, between STERLING FRAZER ASSOCIATES, having an office located at 7352 Nathan Crescent, Niagara Falls, Ontario, Canada L2G 7R6 (hereinafter referred to as SFA) and _____, located or living at,

(Hereinafter referred to as INVENTOR) INVENTOR wishes to disclose the following information (including patent number, where applicable)

_____,
_____,
(Hereinafter called INVENTION) for evaluation by SFA for purposes of performing market research.

Project Overview

Sterling Frazer Associates provides professional market research services that include primary and secondary research either as market reports or focus groups, or combination of the two.

Sterling Frazer Associates' reports are used by government agencies and businesses that may or may not be involved in the assistive technology market.

A typical market report from Sterling Frazer Associates gives an overview of the industry, and works its way to the selected segment of the market that is the focus of the study. We provide both secondary and primary information, that is, information from journals and the Internet, plus we contact industry specific experts (clinical, consumer, or business representatives) to provide their first-hand experience and to identify their wish list of what is missing in the market. Sterling Frazer researchers will interview a minimum of six leaders in the field of gait training and/or ambulatory products for pediatric populations to gather the

latest in research and industry information. Where possible, the contacts will be identified and contact information will be provided. [Note: some interviewees request that they are not identified. In such cases Sterling Frazer will identify these individuals by their qualifications, without giving away who they are.]

Demographic profiles of each market and sub-market are given. Our research goal is to make sure that the largest population has been identified whether they are the primary focus, or potential new markets to cultivate over time.

Market trends of existing products, a list of companies in the industry who currently carry similar products who may be a potential partner in the development and marketing of the product, or, the list will identify companies to avoid due to potential confrontations due to design similarities. Company profiles provide an overview of the company, its history, products, sales (if available), contact information of senior management, and a rating of level of importance to the client's project.



Project Deliverables

Report to include:

1. Overview of the Assistive Technology industry
 - 1.1. General demographics of disabilities in the United States
 - 1.2. Break down of assistive technology by product type
2. Pediatric walker market in North America
 - 2.1. Demographic information specific to the target population
 - 2.2. Growth patterns and trends
 - 2.2.1. Competition – pediatric walking aids (gait trainers and walkers)
 - 2.2.2. Company information
 - 2.2.2.1. Location
 - 2.2.2.2. Company contacts
 - 2.2.2.3. Product descriptions, specifications, and pricing (where available)
3. Listing of adult walker companies¹
4. How to market in the Assistive Technology Industry

¹ Sterling Frazer Associates will make its best effort to identify major manufacturers/distributors of adult walkers world-wide.

- 4.1. Licensing options
- 4.2. Marketing options
- 5. An overview of "how to" market products in the AT field via various distribution channels.
- 6. Conclusion & Recommendations.

Each report becomes the property of the contracting agency (client). Two copies will be provided to the client. Within reason, the client has the ability to have modifications made to the report within one month after delivery. Changes or additions will be discussed in order to determine if they are considered part of the original contract, or if the request is for additional information not discussed in the original plan.



Schedule & Pricing

Payment for this project is \$5,500.00 (USD) to be made to *Sterling Frazer Associates, 7352 Nathan Crescent, Niagara Falls, ON L2G 7R6, Canada.* Payment is made in three installments:

- 50% (\$2500.00) due upon signing,
- 25% (\$1,500.00) due one month into the contract, and
- 25% (\$1,500.00) due upon receipt of the final report.

The INVENTOR will receive the final report no more than two months into the contract.